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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

JONES, DWAYNE C

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/762,630

### Applicant(s)

EMBIL ET AL.

### Examiner

Dwayne C Jones

### Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-21, 30-32, 37 and 38 is/are allowed.
- 6) ☒ Claim(s) 22-29 and 33-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 19-38 are pending.
2. Claims 19-21 and 30-32, 37, and 38 are allowed.
3. Claims 22-29 and 33-36 are rejected.
4. Claims 1-18 are cancelled.

### ***Response to Amendment***

5. The Declaration under 37 CFR 1.132 filed December 29, 2003 is sufficient to overcome the rejection of claims 19-21 and 30-32, 37, and 38 based upon the unexpected results set forth in the declaration.

### ***Claim Objections***

6. Claims 26 and 28 are objected to because of the following informalities: it is requested that the periods “ . ” listed after each letter in the process steps be removed because a claim can only have one period. In addition, it is requested that these periods be replaced with another symbol, such as parenthesis. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 22-25 and 33-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are unclear since independent claims 19 and 30 are limited to compositions "consisting essentially of nimesulide and 17% to 59% by weight of glyceryl monooloein-solvent-phase" and respective groups of claims 22-25 and 33-36 expand the compositions with the broader transitional claim language of "comprising." These anomalies render the claims vague and indefinite.

***Claim Rejections - 35 USC § 103***

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. The rejection of claims 26-29 under 35 U.S.C. 103(a) as being unpatentable over Jain et al. of EP 812,587 A1 possessing a publication date of December 17, 1997 is maintained and repeated for both the above-stated and reasons of record. Jain et al. teach of a non-staining composition of nimesulide, which contains monoglycerides, such as glycerol monooleate, in an amount ranging from 0.5 % to 12 % by weight, (see abstract and page 4, lines 4-13 and 42-43 and page 5, lines 14 and 15). Moreover, Jain et al. teach that it is well known in the art that nimesulide possesses both anti-inflammatory and analgesic properties, (see page 2, lines 5-20). Also, Jain et al. teach of including the presence of hydroxypropyl cellulose as a gelling agent, (see page 4, lines 44-52). Jain et al. also teach of methods of making compositions that contain nimesulide, (see page 4, lines 1-13). In the steps, Jain et al. teach of stirring and mixing

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the nimesulide in order to dissolve the nimesulide. Jain et al. also teach of combining the surfactants, in particular glycerol monooleate, along with the nimesulide mixture by obvious laboratory synthesis reaction techniques, such as stirring, mixing, changing parameters such as pH, pressure or temperature. Furthermore, Jain et al. disclose that these therapeutic compositions may be used as a gel, emulsion, cream, solution, ointment or aerosol, (see page 5, lines 16-29). Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), see also *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). It would have been obvious to one having ordinary skill in the art to optimize the range of the glyceryl monoolein in order to improve the surfactant properties of the sparingly soluble nimesulide. In addition, it is within the purview of the skilled artisan to utilize these topical compositions that contain nimesulide for ailments that are alleviated or treated with a compound that has anti-inflammatory and analgesic properties. In addition, the skilled artisan would have been motivated to formulate compositions of nimesulide with the glycerin monooleate by synthesis techniques that are known in the art, such as stirring, mixing, changing parameters such as pH, pressure or temperature. Accordingly, it would have been obvious to the skilled artisan to perform well known synthesis techniques in order to make formulations that contain nimesulide along with the glycerin monooleate

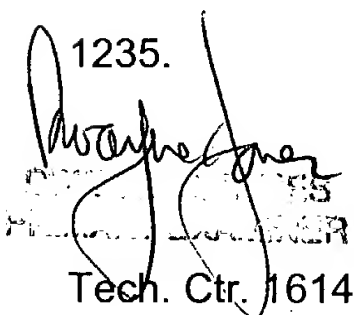
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634 until about February 6, 2004 and then changes to (571) 272-0578. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725 until about February 6, 2004 and then changes to (571) 272-0584. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.



Tech. Ctr. 1614

January 26, 2004